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EXAMINER	
KAROL, JODY LYNN	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,605	WAKAMATSU ET AL.	
	Examiner	Art Unit	
	Jody L. Karol	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/12/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,15,17,18 and 27-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 15, 17-18, and 27-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 11/12/2009. Claims 1-11, 13-14, 16 and 19-26 are cancelled. Claims 31-52 are newly added. Claims 12, 15, 17-18, and 27-32 are pending and are currently under consideration.

WITHDRAWN REJECTIONS

1. Applicant's cancellation of claims 1, 5, 7-10, and 21-26 renders the provisional rejection of claims 1, 5, 7-10, and 21-26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6 of copending Application No. 11/722,965 moot. Thus, said rejection is herein withdrawn.

2. Applicant's cancellation of claims 1, 5, 7-10, and 21-26 renders the rejection of claims 1, 5, 7-10, and 21-26 under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al. (WO 2002/41853) in view of Castiel et al. (US 2002/0042380 A1) moot. Thus, said rejection is herein withdrawn.

REJECTIONS

3. The following rejections and/or objections are either reiterated from the previous Office Action dated 5/12/2009 or newly applied. They constitute the complete set of rejections and/or objections presently being applied in the instant application. The newly applied rejections are necessitated by newly added claims 31-52.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 12, 15, 17-18, and 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al. (WO 2002/41853) in view of Castiel et al. (US 2002/0042380 A1). US 6,946,436 B2 is used as the English equivalent of Wakamatsu et al. (WO 2002/41853).

The instant claims are directed to methods of potentiating an anti-aging action of a composition comprising ascorbic acid 2-glucoside comprising incorporating an adenosine monophosphate or salt thereof into the composition and methods for retarding skin aging comprising applying to the skin ascorbic acid 2-glucoside and adenosine monophosphate or salt thereof.

Wakamatsu et al. teach an O/W emulsion composition comprising an electrolyte, where the preferred electrolytes are adenosine monophosphate, cyclic adenosine monophosphate, salts thereof, ascorbic acid, and derivatives thereof (see column 7, lines 9-36 and claims 3-4). The adenylic acid derivatives (i.e. adenosine monophosphate) are known to exhibit moisturizing and anti-aging effects when applied to the skin (see column 7, lines 45-54 and column 16, lines 1-15). The placing of the phosphate group of adenosine monophosphate (AMP) is not specified, however, a phosphate group can only attach on an adenosine molecule where there is a hydroxyl group. Hydroxyl groups are present on adenosine at the 2', 3' and 5' positions, so the

AMP must be adenosine 2'-monophosphate, adenosine 3'-monophosphate, adenosine 5'-monophosphate, or mixtures thereof. Wakamatsu et al. further teach that the electrolytes can be used alone or in combination of two or more species (see column 7, lines 39-40) and the amount of electrolytes contained in the composition is not limited, but is at least 0.1% by weight, and preferably 0.5 to 7% by weight as claimed in the instant claims 7-9 and 23-25 (see column 7, line 66 to column 8, line 5 and claims 12-14). Wakamatsu et al. teaches specific examples where adenosine monophosphate disodium is present in the composition in 1.5%, 3.0% and 6.0% by weight (see Table 1, examples 1-4) and where sodium L-ascorbic acid phosphate ester (L-ascorbyl phosphate salt) is present in the composition in 2.0 and 3.0% by weight (see Table 1, examples 5-6).

Wakamatsu et al. do not teach compositions comprising ascorbic 2-glucoside, or that ascorbic 2-glucoside is an acceptable ascorbic acid derivative. Wakamatsu et al. do not explicitly teach adenosine 5'-monophosphate as claimed in the instant claims 15 and 36. Wakamatsu et al. do not teach the method of potentiating an anti-aging effect by incorporating AMP into a composition comprising ascorbic 2-glucoside as claimed in the instant claims 12, 15, 17, and 31-34. Wakamatsu et al. do not teach the method applying the herein claimed composition to the skin to prevent aging as claimed in the instant claims 18 and 35-41.

Castiel et al. teach Vitamin C derivatives that are more stable than ascorbic acid itself and which combat or prevent intrinsic aging of the skin (see abstract). One of the preferred ascorbic acid derivatives is a 2-O-α-D-glucopyranosyl of ascorbic acid, also

known as ascorbic acid 2-glucoside (see page 2, sections 32, 35, and 41). Ascorbic 2-glucoside is known to be useful as a depigmenting agent (see pages 1-2, section [0021]). Castiel et al. further teaches the compositions contain 0.001 to 10% by weight of ascorbic acid derivatives (see page 2, section 42), and gives an example of a composition with ascorbic acid 2-glucoside present in 0.1% by weight of the composition (see page 4, section 77).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine adenosine monophosphate with another electrolyte, such as an ascorbic acid derivative, as taught by Wakamatsu et al., wherein the ascorbic acid derivative is ascorbic acid 2-glucoside as taught Castiel et al. One of ordinary skill in the art would have been motivated to do so in order to formulate a composition with anti-aging action, since adenosine monophosphate derivatives and ascorbic acid derivatives are both used individually in the art for the same purpose, namely to keep skin from aging. It is obvious to one of ordinary skill in the art to combine components taught individually in the art as having the same purpose to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980). In regards to claims 12, 15, 17, and 31-34, the combination of ascorbyl 2-glucoside and adenosine monophosphate used for the same purpose of anti-aging action, is expected to have up to an additive effect. Thus the anti-aging action of ascorbyl 2-glucoside is considered to be enhanced by combination with adenosine monophosphate.

In regards to claims 18, and 35-41, it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the composition obvious over Wakamatsu et al. in view of Castiel et al. to the skin for its intended use to retard aging. One of ordinary skill in the art would have been motivated to retard skin aging by applying the composition Wakamatsu et al. in view of Castiel et al. to the skin with a reasonable expectation of success because it is obvious to use a composition for its intended used.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

6. Claims 27-30 and 42-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al. (WO 2002/41853) in view of Castiel et al. (US 2002/0042380 A1) as applied to claims 12, 15, 17-18, and 31-41 above and in further view of Quan et al. (US 6,180,133 B1).

Claims 27-29 and 42-45 are directed to methods of potentiating a skin pigmentation alleviating action of a composition comprising ascorbic acid 2-glucoside comprising incorporating an adenosine monophosphate or salt thereof into the composition. Claims 30 and 46-52 are directed to method for alleviating skin pigmentation comprising applying to pigmented skin ascorbic acid 2-glucoside and adenosine monophosphate or salt thereof.

Wakamatsu et al. in view of Castiel et al. is described *supra* as applied to claims 12, 15, 17-18, and 31-41.

Wakamatsu et al. and Castiel et al. do not teach potentiating a skin pigmentation alleviating action of a composition comprising ascorbic acid 2-glucoside comprising incorporating an adenosine monophosphate or salt thereof into the composition or alleviating skin pigmentation comprising applying to pigmented skin ascorbic acid 2-glucoside and adenosine monophosphate or salt thereof.

Quan et al. teach that aging of the skin is caused by a combination of extrinsic and intrinsic factors, and may be characterized by wrinkling of the skin, uneven or hyperpigmentation, loss of distensibility and uneven texture *inter alia* (see column 2, lines 3-47).

It would have been obvious to one of ordinary skill in the art at the time of the invention, to potentiate a skin pigmentation alleviating effect by adding adenosine monophosphate to ascorbic 2-glucoside as obvious over Wakamatsu et al. in view of Castiel et al. because Quan et al. teach uneven and/or hyperpigmentation of the skin are signs of skin aging. One of ordinary skill in the art would have been motivated to add by adding adenosine monophosphate to ascorbic 2-glucoside to form a composition for treating aging and skin pigmentation. One of ordinary skill in the art would have had a reasonable expectation of success of adding adenosine monophosphate to ascorbic 2-glucoside to potentiate a skin pigmentation alleviating effect because both adenosine monophosphate and ascorbic 2-glucoside are taught by Wakamatsu et al. and Castiel et al. to have anti-aging action, ascorbic 2-glucoside is taught by Castiel et al. to be a depigmenting agent, and skin aging is characterized by uneven and/or hyperpigmentation of the skin as taught by Quan et al. Thus it can be reasonably

expected that in enhancing the anti-aging action of ascorbic 2-glucoside by adding adenosine monophosphate, the skin pigmentation alleviating effect is also enhanced.

Furthermore, in regards to claim 30 and 46-52, it would have been obvious to one of ordinary skill in the art to apply the composition comprising ascorbic 2-glucoside and adenosine monophosphate as obvious over Wakamatsu et al. in view of Castiel et al. to pigmented skin to alleviate skin pigmentation. One of ordinary skill in the art would have been motivated to apply the composition comprising ascorbic 2-glucoside and adenosine monophosphate as obvious over Wakamatsu et al. in view of Castiel et al. to pigmented skin to treat pigmented skin associated with aging. One of ordinary skill in the art would have had a reasonable expectation of success in alleviating skin pigmentation by applying the composition comprising ascorbic 2-glucoside and adenosine monophosphate as obvious over Wakamatsu et al. in view of Castiel et al. to pigmented skin because ascorbic 2-glucoside and adenosine monophosphate are taught by Wakamatsu et al. and Castiel et al. to have anti-aging action, ascorbic 2-glucoside is a depigmenting agent as taught by Castiel et al., and skin aging is characterized by uneven and/or hyperpigmentation of the skin as taught by Quan et al.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

7. Applicant's arguments filed 11/12/2009 have been fully considered but they are not persuasive.

Applicant argues that Castiel et al. does not specifically teach ascorbyl 2-glucoside is an anti-aging agent, and rather ascorbyl 2-glucoside is a depigmenting agent that augments epidermal lipogenesis. The Applicant further argues that when referring to anti-aging properties, Castiel et al. refers to a general, large class of compounds defined as ascorbic acid derivatives, not to ascorbyl 2-glucoside, and that Castiel et al. provides no reason for specifically selecting ascorbic acid 2-glucoside for used in the claimed methods of preventing aging. In response it is respectfully submitted that the instant specification defines the term "anti-aging" in connection with the invention as retarding skin aging, particularly alleviating skin pigmentation (see page 10, section [055]). Thus, skin depigmenting agents, such as ascorbyl 2-glucoside, are considered to have an "anti-aging" effect. Furthermore, Castiel et al. specifically the ascorbic acids derivatives according to the invention may be administered for combating the intrinsic aging of skin (see page 3, section [0045]) wherein ascorbyl 2-glucoside is taught as a preferred ascorbic acid derivative (see page 2, section [0035]). Moreover, Castiel et al. teaches a specific formulation example comprising ascorbyl glucoside for improving the suppleness of skin and to smooth wrinkles and fine lines (see page 4, sections [0077]-[0078]). Thus, one of ordinary skill in the art would reasonably ascertain from the teachings of Castiel et al. and from the information provided in the instant specification, that ascorbyl 2-glucoside has an "anti-aging" action. It is also noted that the claims are drawn to potentiating an anti-aging action and retarding aging, but not to preventing aging, as stated on page 10 of the remarks.

The Applicant argues that Wakamatsu et al. teach ascorbic acid as only one of several electrolytes without pointed to any of those electrolytes as more beneficial to use than another. In response it is respectfully submitted that the motivation to use ascorbic acid is derived from Castiel et al., which teach stable ascorbic acid derivatives with anti-aging action. Adenosine monophosphate is also specifically taught by Wakamatsu et al. to have an anti-aging action. Thus, the combination of adenosine monophosphate with ascorbic 2-glucoside is on the basis that both components have an anti-aging action. It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980).

The Applicant further argues that the combination of Wakamatsu and Castiel fails to suggest the synergistic effects disclosed in the instant specification. The Applicant first alleges that because AMP derivatives and ascorbic acid compounds act through different mechanism, it would not have been obvious that the combination of an AMP derivative and ascorbyl 2-glcuoside would produce and "additive effect." In response it is respectfully submitted that regardless of the mechanism of action, ascorbic 2-glucoside and adenosine monophosphate are taught by Wakamatsu et al. and Castiel et al. to have skin anti-aging action. Combination therapy is often employed using components that act via different mechanism to achieve a greater effect than with the individual components alone. Thus, the mechanism of action of each component does not detract from the aging effect of each component, and up to an additive effect is still expected.

The Applicant further argues that the data presented in Figure 1 of a synergistic effect supports the full scope of the claims, and there is no reason to suggest that the data represented in Figure 1 is not reflective of a trend that each of the forms of AMP listed in the instant claims 12 and 18 potentiates the action of ascorbyl 2-glucoside. The Examiner respectfully disagrees. As previously stated in 5/12/2009 Office Action, it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the "evidence" of alleged synergism is not commensurate with the breadth of the claims. Only one specific comparative example is provided on pages 22-24 of the instant specification, and in Figure 1, as evidence for combining ascorbic-2-glucoside and AMP in 20% isopropanol to synergistically potentiate the effect of alleviating pigmentation. Furthermore, the Example only tests the effect of alleviating pigmentation wherein 2% of each of the components is present. One example with a specific amount of each component does not provide sufficient evidence that the remaining compositions possible under the claim scope would exhibit the same of similar results. For example, the Example does not provide sufficient evidence that a

composition comprising 10% by weight AMP and 10% by weight ascorbyl 2-glucoside would have a similar synergistic effect in alleviating skin pigmentation. Moreover, a trend in the results cannot be ascertained from a single data point demonstrating a synergistic effect at one concentration. Therefore, no clear and convincing unexpected benefit is seen to be present herein.

The Applicant also alleges the Office attempts to dismiss the specification's proof of a synergistic effect by questioning the link between the improvement in skin brightness and the anti-aging element of the rejected claims. In response it is respectfully acknowledged that an "anti-aging" action means "retarding skin aging, particularly alleviating skin pigmentation" as stated on page 10, section [055] of the instant specification.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/Yong S. Chong/
Primary Examiner, Art Unit 1627